

## **REMARKS**

Claims 1 through 17, 19 through 36 and 38 are currently pending in this amendment. This amendment cancels claims 9, 12, 17, 24, 28, 35, and 36. Therefore, upon entry of this amendment, claims 1 through 7, 10 through 11, 13 through 16, 19 through 23, 25 through 27, 29 through 34 and 38 will remain pending.

Claims 1 through 6, 10, 11, 13, 14, 19 through 23, 25, 26, 29 through 32 and 38 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,559,189 to Baker, Jr. et al. (Baker).

Baker is directed to compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses. Primarily, the Baker invention, as evidenced by the Examples and the claims, is oil-in-water emulsion compositions and methods for decontaminating a sample with such emulsion compositions.

Claim 1 recites a tampon comprising an absorbent material and a composition disposed in the absorbent material. The composition has at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon and at least one finishing agent in an amount of about 0.01 wt.% to about 10 wt.% of the total weight of the tampon. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Claim 20 recites a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing *Staphylococcus aureus* bacteria to a tampon having an absorbent material and a composition comprising at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon and at least one finishing agent in an amount of about 0.01 wt.% to about 10

wt.% of the total weight of the tampon. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduces *Staphylococcus aureus* bacteria growth.

Applicants respectfully submit that Baker does not disclose each and every element of the claimed invention and therefore does not anticipate the claimed invention under §102(e). Discussed above, Baker's primary focus is oil-in-water emulsion compositions and methods for decontaminating a sample with such emulsion compositions, as evidenced by their detailed description of the invention, examples and the claims. As conceded by the Action (page 6), however, Baker remains silent as to the claimed components with respect to the total weight of the tampon. Moreover, Baker fails to disclose or suggest the claimed amounts of components that are synergistically effective to neutralize the production of TSST-1 and to reduce *Staphylococcus aureus* bacteria growth, as in claimed invention. Accordingly, Baker does not anticipate claim 1.

Further, while Baker discloses tampon the potential use of the oil-in-water emulsions in medical devices, buried in a laundry list of possible medical devices is a tampon. The laundry list disclosure of a tampon is the only reference to a tampon in the entire Baker patent, which is over 80 pages long. The mere mention of an element of the claimed invention in a piece of prior art, buried in a long list of possible combinations of products and chemical solutions, does not describe the claimed invention with enough detail and clarity to disclose it to a person having ordinary skill in the art. Such a passing mention does not release the information to the public and thus can not anticipate the claimed invention under §102(e). See In re Wiggins, 179 U.S.P.Q. 421, 425 (C.C.P.A. 1973); In re Schoenwald, 22 U.S.P.Q.2d 1671, 1671 (Fed. Cir. 1992).

In the instant case, the mere mention of a tampon buried in a long list of other possible products that can be used with Baker's oil-in-water emulsion compositions

clearly fails to disclose or suggest the claimed invention to one of ordinary skill in the art. Moreover, nowhere in Baker is a disclosure or suggestion of the use of a tampon with at least one antibacterial agent and at least one finishing agent that synergistically neutralizes TSST-1 toxin and reduces *Staphylococcus aureus* bacteria growth, as claimed. Therefore, Baker does not anticipate the claimed invention.

Applicants further submit that the Office Action incorrectly concludes that Baker inherently discloses the treatment of TSST-1 toxin by the claimed invention. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). Contrary to the requirement for inherency, the present invention is the result of unexpected findings. Notably, as described in the present specification (page 13), it was found that tampons with the claimed concentrations of anti-bacterial agent and finishing agent significantly reduced the growth of *S. aureus* bacteria, compared to the innoculum control, by greater than 7 logs from the average of  $1.4 \times 10^9$  CFU/ml.

Ignoring the synergistic properties of the present invention, the Action clearly fails to cite any rationale or extrinsic evidence found in Baker, or anywhere else to make clear the missing elements of the claimed invention. Baker's composition does not possess the synergistic TSST-1 toxin neutralization and *Staphylococcus aureus* antibacterial properties unexpectedly found with the presently claimed composition. As explained above, Baker merely discloses the possible use of an oil-in-water emulsion in a medical device, such as tampon. The mere fact that a certain may result from a given set of circumstances, however, is not sufficient. *In re Robertson*, 169 F.3d. 743, 745, 49 USPQ2d 1949, 1950-1951 (Fed. Cir. 1999) (citation omitted).

Furthermore, Baker is silent as to claimed concentrations of anti-bacterial agent and finishing agent per wt.% of tampon, which is even more evidence that Baker fails to inherently possess the missing elements of the present invention. Therefore, the Action impermissibly relies on a mere possibility that the claimed properties may possibly, but not admittedly, be capable in the cited prior art. Absent any extrinsic evidence making clear that the claimed properties are necessarily present in Baker, the Action cannot and does not establish inherency. It is only through the present application that a tampon with such a composition having synergistic neutralization and antibacterial properties is disclosed or suggested.

Accordingly, for at least the reasons set forth above, Baker fails to anticipate claims 1 through 6, 10, 11, 13, 14, 19 through 23, 25, 26, 29 through 32 and 38. As such, Applicants respectfully request that reconsideration and withdrawal of the §102(e) rejection of these claims.

Claims 7 through 9, 24, 27 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker. This amendment cancels claims 8, 9, 24 and 28, rendering the rejection over the canceled claims moot.

Dependent claim 7 depends indirectly from claim 1. Dependent claim 27 indirectly depends from claim 20. Both claims recite the feature that one or more quaternary ammonium compounds are present in an amount of about 1.0 wt.% based on the total weight of the tampon. Again, contrary to Baker, which merely describes a composition, the present invention is directed a composition *on a device*, namely a tampon. While Baker mentions about in a passing reference to a tampon, Baker describes nothing about how to apply the composition *to a device*, or how much of the composition directed to a particular type of toxin. Satisfying this need, the present invention describes the appropriate inventive steps, and the composition and the process are not obvious to one ordinarily skilled in the art.

Applicants respectfully submit that, as noted above, Baker fails to disclose or suggest the claimed invention recited in at least independent claims 1 and 20. Therefore, it follows that Baker also fails to disclose or suggest the claimed invention recited in claims 7 and 27, as these claims depend either directly or indirectly from claims 1 and 20.

Further, Applicants respectfully submit that the claimed features recited in claims 7 and 27 are not disclosed or suggested in Baker. As conceded by the Action, Baker is silent as to the amount of antibacterial agent based on the total weight of a tampon. This deficiency in Baker is not surprising because Applicant's claimed invention is the result of unexpected results. Namely, antibacterial agent present in the claimed amounts in combination with at least one finishing agent in the claimed amounts yields a tampon with synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and to reduce *Staphylococcus aureus* bacteria growth. The claimed synergistic properties are clearly set forth in the data detailed on pages 12 and 13 of the present specification.

To the contrary, there is no disclosure or suggestion anywhere in Baker of the claimed tampon having the antibacterial agent present in such an amount in conjunction with at least one finishing agent that results in synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth. Therefore, Baker does not render the claimed invention obvious.

In lieu of the above, Applicants respectfully submit that claims 7 and 27 are patentably distinguishable over Baker. As such, reconsideration and withdrawal of the §103(a) rejection of these claims is respectfully requested.

Claims 12, 17, 35 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker. This amendment cancels claims 12, 17, 35 and 36, rendering the rejection over the canceled claims moot.

Claims 15, 16, 33 and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker as applied to claims 14 and 32 above, and further in view of U.S. Patent No. 6,335,012 to Fischetti et al. (Fischetti).

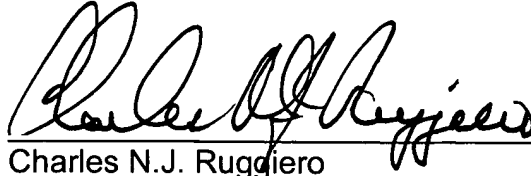
Baker is summarized above. Fischetti is directed to a method for treating dental caries comprising administering a composition comprising an effective amount of at least one lytic enzyme produced by a bacteriophage specific for the bacteria.

As stated above, claims 1 and 20 are patentably distinguishable over Baker, as Baker fails to disclose or suggest the claimed invention. Furthermore, Fischetti fails to cure any deficiencies of Baker because Fischetti also fails to disclose or suggest the claimed invention. Therefore, the combination of Baker and Fischetti does not render claims 1 and 20 obvious. Accordingly, claims 15, 16, 33 and 34, which depend directly or indirectly therefrom, are not rendered obvious by Baker taken alone or in combination with Fischetti.

In view of the foregoing, Applicants respectfully submit that all claims presented in this application are patentably distinguishable over the cited prior art, taken alone or in combination. Accordingly, Applicants respectfully request favorable consideration and the passage of the application to allowance.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

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